510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92. The summary was prepared on 4 April 2005.

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765 USA Tel: (800) 729-9010 Fax: (909) 839-8804
Contact:	Michael A. Johnson
Trade (Proprietary) Name:	Coronary Sinus Deflectable Mapping Catheter
Common Name:	Electrophysiology Diagnostic Mapping Catheter
Classification Name:	Electrode Recording Catheter (21 CFR 870.1220)
Device Class:	II
Product code:	DRF
Predicate device:	K892265 Biosense Webster Deflectable Mapping Catheter

Product Description:
The Coronary Sinus Deflectable Mapping Catheter is a 10 pole deflectable mapping electrophysiology (EP) catheter with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The pre-shaped tip MZ curve facilitates introduction of the catheter into the Coronary Sinus Ostium when approaching the Right Atrium through the inferior Vena Cava. This catheter includes a handle with a thumbknob, which allows deflection of the distal end of the catheter. The handle also has a 10 pin connector for interfacing to a recording system through a standard catheter cable. The catheter has a braided shaft and a distal tip that is unbraided to impart flexibility and softness, which enhances safety to the patient by reducing the chance of perforation. The catheter will be provided in 4, 5, 6 and 7 french sizes with either 2-5-2 or 2-8-2 electrode spacing.

Intended Use:
The Coronary Sinus Deflectable Mapping Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only.

Summary of substantial equivalence:
The Coronary Sinus Deflectable Mapping Catheter has the same material specifications as the predicate device. The modification is the addition of a "Shepard's Hook" (MZ curve) on the distal end of the catheter. The materials are the same as the predicate; the modified device uses the same fundamental technology, energy source, and has the same intended use as the predicate device.

Testing:
The modified device was assessed with non-clinical bench tests to verify conformance with design and performance specifications. Tests included those conducted to test performance and integrity after the device had been subjected to accelerated aging equivalent to 1 year of real time aging.

Biocompatibility and sterilization validation are the same as the predicate device. Patient-contact materials are identical to the predicate device and the device change does not affect the ability to sterilize the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2005

Biosense Webster, Inc.
c/o Mr. Michael A. Johnson
Regulatory Affairs Specialist
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K050877
Trade Name: Coronary Sinus Deflectable Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrophysiology Diagnostic Mapping Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: June 1, 2005
Received: June 2, 2005

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K050877

Device Name: Coronary Sinus Deflectable Mapping Catheter

Indications for Use: The Coronary Sinus Deflectable Mapping Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Summanwala for

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050877